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No. 08-889

IN THE

Supreme Court of the United States

TRI-UNION SEAFOODS, L.L.C.
D/B/A CHICKEN OF THE SEA,

Petitioner,

v.

DEBORAH FELLNER,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

REPLY TO BRIEF IN OPPOSITION

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TABLE OF CONTENTS

Page

REPLY TO BRIEF IN OPPOSITION.....1

CONCLUSION 12

TABLE OF AUTHORITIES

CASES

Page

Altria Group, Inc. v. *Good*, 129 S. Ct. 538 (2008) 9

Arkansas Electric Cooperative Corp. v. *Arkansas Public Service Commission*, 461 U.S. 375 (1983) 9

Dowhal v. *SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (2004) 1, 6, 7

Grocery Manufacturers of America, Inc. v. *Gerace*, 755 F.2d 993 (2d Cir. 1985) 10

Puerto Rico Department of Consumer Affairs v. *Isla Petroleum Corp.*, 485 U.S. 495 (1988) 9

Wyeth v. *Levine*, 173 L. Ed. 2d 51 (2009) 1, 7, 8, 10

STATUTES & REGULATORY MATERIALS

21 U.S.C. § 342 3

21 U.S.C. § 343 5

44 Fed. Reg. 3,990 (Jan. 19, 1979) 3

EPA-823-R-04-005 (March 2004) 3, 4, 5

REPLY TO BRIEF IN OPPOSITION

As demonstrated by the amicus briefs filed by the Chamber of Commerce of the United States of America and the National Fisheries Institute, the federal preemption issues raised in the Petition are important. The court of appeals determined that a series of actions by the Food and Drug Administration ("FDA") that reflect a considered regulatory policy against including warnings about the risks of methylmercury on tuna-product labels are insufficiently authoritative to preempt state law. Respondent's strained attempt to distinguish this case from *Dowhal* v. *SmithKline Beecham Consumer Healthcare*, in which the California Supreme Court held that a similar FDA policy was sufficiently "definite and authoritative" to preempt state law, only highlights the need for this Court's review. 88 P.3d 1, 9 (2004)

This Court's recent decision in *Wyeth* v. *Levine* does not "confirm[]" (Opp. 10) that the court of appeals' decision was correct. 555 U.S. __, 173 L. Ed. 2d 51 (2009). In *Wyeth*, this Court refused to accord deference to FDA's view, conveyed in a preamble to a regulation, that the respondent's tort claim was preempted, because FDA failed to provide interested parties "notice or opportunity for comment" and "reverse[d] [its] own longstanding position without providing a reasoned explanation." *Id.*, slip op. at 21. Here, by contrast, FDA's view that including warnings about the risk of methylmercury on tuna-product labels would frustrate its longstanding policy has been subject to notice and an opportunity to comment and is supported by a reasoned, consistent position. *Wyeth* therefore does not resolve the

important question whether FDA's longstanding and consistent policy against mercury warning labels on seafood products is sufficiently authoritative to preempt contrary state law.

Requiring warnings on tuna-product labels not only frustrates FDA's regulatory approach but also makes it impossible for petitioner to comply with both state and federal law. The court of appeals (Pet. App. 34a) and respondent (Opp. 12) dismiss this problem on the ground that FDA has not taken any enforcement action under its misbranding authority. But petitioner should not be required to wait until it has actually been subjected to liability where, as here, the federal policy is authoritative and the implications of complying with conflicting state requirements are clear.

Respondent's belief (Opp. 14) that some type of warning (other than the Proposition 65 warning that FDA squarely rejected) could be crafted that would not violate FDA's approach ignores the rationale for FDA's position in the California litigation. FDA explained that a warning purporting to convey factual information about the harms caused by methylmercury on a tuna-product label would be "misleading" because there is no "scientific basis as to the possible harm caused by [tuna products], or as to the amounts of such foods that would be required to cause this harm." Letter to Bill Lockyer, Attorney General of the State of California, http://www.cfsan.fda.gov/~dms/fl-ltr65.html. ("FDA Letter").

1. Respondent seeks to defend the court of appeals' decision by minimizing the role FDA has played in regulating methylmercury in seafood. Far

from having taken only a "few informal actions" (Opp. 1), however, FDA, pursuant to its statutory authority to regulate food products, has been addressing the issue for thirty years. In 1979, the FDA established an action level for the amount of mercury in seafood (1.0 part per million) and determined that seafood exceeding that threshold is subject to being treated as "adulterated" under 21 U.S.C. § 342. *See* 44 Fed. Reg. 3,990, 3,993 (Jan. 19, 1979). Since that time, FDA has studied methylmercury in seafood intensively and has taken a series of actions that reflect its considered judgment that consumer advisories rather than product-label warnings should be used to inform the public about the risks of methylmercury.

First, FDA issued an advisory on methylmercury in fish in 1995 in which it contrasted "eating a variety of types of fish, the normal pattern of consumption," which "does not put anyone in danger of mercury poisoning" with "fad diets—frequently eating only one type of food or a particular species of fish—"which place such dieters "at risk." C.A. App. A155.

Second, nine years later, FDA and the Environmental Protection Agency (EPA) issued a joint Advisory, which remains current, that emphasizes the health benefits of seafood and encourages "women and young children in particular" to "include fish or shellfish in their diets due to the many nutritional benefits." EPA-823-R-04-005, http://www.cfsan.fda.gov/~dms/admehg3.html (March 2004). The Advisory further explains that "[f]or most people, the risk from mercury by eating fish and shellfish is not a health concern." *Id.*

At the same time, the Advisory warns that "some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system." *Id.* To address that risk, FDA and EPA provide detailed recommendations for women and young children, who are advised (1) not to eat certain fish that contain high levels of mercury (shark, swordfish, king mackerel, and tilefish); (2) to eat up to 12 ounces a week of a variety of fish and shellfish that are lower in mercury (including canned light tuna), or up to 6 ounces per week of albacore tuna; and (3) to eat no more than 6 ounces per week of fish caught by family or friends in local water in the absence of a local advisory providing specific advice. *See* Pet. 5-6.

Third, in September 2004, FDA, after providing notice and an opportunity to comment, rejected a petition filed by Martek Biosciences Corporation seeking to require that any qualified health claim concerning fish products, including tuna products, be accompanied by a statement warning of the possible harmful effects of mercury to pregnant women, women of childbearing age, nursing mothers, and young children.[1] In doing so, FDA explained that "the advisory approach" it has adopted "is more effective than a product label statement in relaying

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[1] Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Martin J. Hahn, Hogan & Hartson, LLP (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0002-vol13.pdf ["FDA Martek Petition Denial"]; Letter from William K. Hubbard, Assoc. Comm'r for Policy & Planning, FDA, to Jonathan W. Emord, Emord & Associates, PC (Sept. 8, 2004), http://www.fda.gov/ohrms/dockets/dockets/03q0401/03q-0401-ans0001-vol13.pdf.

the complex messages about mercury in fish and shellfish." FDA Martek Petition Denial 28-29. Even more problematic, a product-label warning could cause "confusion" stemming from the different warnings that would accompany certain types of commercial fish on the one hand and locally caught fish on the other. *Id.* at 29. In addition, a warning on the product label could produce "unintended adverse public health consequences" by deterring non-vulnerable individuals from consuming fish products, which carry significant health benefits. *Id.*

Finally, consistent with the 2004 Advisory and Martek Petition Denial, the Commissioner of the FDA in August 2005 wrote a letter to the California Attorney General setting out FDA's position that a lawsuit seeking to require warnings about mercury on tuna-product labels under California's Proposition 65 was preempted by FDA's regulatory approach. FDA Letter. Citing the same concerns that led it to reject the Martek Petition, the Commissioner explained that FDA has "deliberately implemented its regulatory authority with a nuanced approach, relying primarily on disclosure of ingredient information and nutrition information on labels and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels." *Id.* at 6. With respect to methylmercury in fish products in particular, the Commissioner noted, FDA0020has adopted a "carefully considered approach of advising consumers of both the benefits and possible risks of eating seafood." *Id.* In FDA's view, the California lawsuit both "frustrate[s]" that approach and would render tuna products "misbranded" under federal law, 21 U.S.C. § 343,

because the proposed warnings "purport to convey factual information" about the risks of methylmercury "without any scientific basis as to the possible harm caused by [tuna products], or as to the amounts of [tuna products] that would be required to cause this harm." FDA Letter at 6.[2]

2. In the light of this longstanding and consistent FDA policy against including warnings about methylmercury on tuna-product labels, the court of appeals' holding that FDA's actions were too informal to be authoritative conflicts with *Dowhal*. In *Dowhal*, the California Supreme Court accorded preemptive effect to an FDA letter that rejected the plaintiff's citizen petition to the extent it sought to require a particular warning about the effects of nicotine-replacement-therapy (NRT) products on unborn children. Instead, the letter directed NRT manufacturers to use a warning that the agency had previously approved. The *Dowhal* court ruled that the FDA letter was sufficiently "definite and authoritative" to preempt state law, because "it is apparent from the tenor of the letter that it imposes a duty on defendants." 88 P.3d at 9-10.

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[2] Respondent (Opp. 4) seeks to impugn the integrity of the Commissioner's letter on the ground that it relied on a letter from counsel for the tuna industry defendants in the California litigation. A presumption of regularity attends agency action, however, and the agency was free to accept or reject the views of the tuna industry. Moreover, the Commissioner's letter relied on the reasoning of the Martek Petition Denial, which was issued after all interested parties had an opportunity to comment. *See* FDA Letter at 5-6 & n.7.

Respondent contends (Opp. 10) that the court of appeals' decision does not conflict with *Dowhal* because FDA's actions here imposed no duty on "[petitioner] or anyone else." Respondent is incorrect. It is equally "apparent from the tenor" of the Commissioner's Letter, the Martek Petition Denial, and the regulatory approach on which they are based, that federal law requires petitioner to refrain from adding to its tuna-products label a warning about the risks of methylmercury.[3]

Because FDA's policy against including warnings about methylmercury on seafood products is no less formal, authoritative, or definitive than FDA's denial of the citizen petition in *Dowhal*, there is a conflict between that decision and the decision below. Contrary to respondent's suggestion (Opp. 10), this Court's decision in *Wyeth* does not "confirm[]" that the court of appeals' decision was correct.

First, the Court in *Wyeth* held that the drug manufacturer failed to offer "clear evidence" that FDA would have rejected a change to Phenergan's label. *Wyeth*, slip op. at 15. Here, by contrast, there *is* clear evidence that FDA would reject a label warning about the risks of methylmercury in tuna products as antithetical to its "carefully considered approach." FDA Letter at 6.

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[3] Respondent contrasts (Opp. 10) the allegedly "informal" nature of the Commissioner's letter with the "formality" of the denial of the citizen petition in *Dowhal*. As noted above, however, the Commissioner's Letter relied heavily on the reasoned explanation that FDA provided in denying the Martek Petition, after notice and an opportunity for comment.

Second, this Court refused to defer to FDA's view that state tort law actions challenging labels approved by the FDA are preempted because that view was adopted "without offering States or other interested parties notice or opportunity for comment" and because the view "reverse[d] the FDA's own longstanding position without providing a reasoned explanation." *Wyeth*, slip op. at 21. Here, by contrast, FDA's deliberate decision to regulate methylmercury through consumer advisories rather than warnings was subject to notice and an opportunity to comment. *See* Martek Petition Denial.

In that formal process, FDA set out its rationale for that approach, including its view that consumer advisories are "more effective than a product label statement in relaying the complex messages about mercury in fish and shellfish"; warnings would not contain the "level of clarity and detail" that advisories contain; warnings would cause "confusion"; and "a label statement that reaches the public at large can . . . have unintended adverse public health consequences." Martek Petition Denial 28-29. The Commissioner's Letter, in which he articulated FDA's view that Proposition 65 warnings were preempted, was a logical extension of the Martek Petition Denial, which had explained why warnings would undermine the FDA's regulatory approach. As such, it is entitled to more deference than the "inherently suspect" agency views in *Wyeth*, slip op. at 21. The decision in *Wyeth* therefore does not eliminate the need for review of the court of appeals' decision, which refused to accord preemptive effect to FDA's longstanding and consistent policy

against warnings about methylmercury on tuna-product labels.

Contrary to respondent's suggestion (Opp. 12), petitioner is not asking this Court to draw "exaggerated inferences" from its statement in *Arkansas Electric Cooperative Corp.* v. *Arkansas Public Service Commission*, 461 U.S. 375, 384 (1983), that "a federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated." Indeed, the Court need not go as far as that basic proposition would permit. Here, FDA has made its policy against warnings explicit. FDA has not merely forgone requiring warnings; it has explained why warnings would undercut its regulatory approach.

This case is thus a far cry from *Puerto Rico Department of Consumer Affairs* v. *Isla Petroleum Corp.*, 485 U.S. 495 (1988) (cited at Opp. 12), where the Court declined to find that certain gasoline price regulations were preempted in "the absence of *any extant federal regulatory program with which the state regulation might conflict.*" *Id.* at 500 (emphasis added). It is clear that FDA has a regulatory policy governing methylmercury in seafood. It is also clear that FDA's policy will not countenance warnings about methylmercury on tuna-product labels. The only question is whether that policy is sufficiently authoritative to carry preemptive force, and that question merits this Court's review. *See* Brief of the Chamber of Commerce of the United States of America as *Amicus Curiae* in Support of Petitioner, *Tri-Union Seafoods, L.L.C.* v. *Fellner*, No. 08-889, at 20-22 (noting that in *Altria Group, Inc.* v. *Good*, 129

S. Ct. 538 (2008), this Court granted review of question whether "the agency's action was too 'informal' to preempt conflicting state law" but ultimately found it unnecessary to resolve that question).

3. This Court should grant review for the additional reason that the court of appeals' decision places petitioner in the untenable position of facing exposure to state tort liability as the price for complying with federal law. Respondent downplays petitioner's predicament, pointing out that FDA has not "enforce[ed] the statutory prohibition on misbranded food." Opp. 12. But petitioner has not given FDA a reason to do so because it has complied with FDA's policy against including warnings about methyl-mercury on its tuna-product labels. Moreover, state law is preempted when it is "impossible for [the regulated party] to comply with both federal and state requirements." *Wyeth*, slip op. at 15. It has never been the rule that a party must suffer federal penalties to establish what federal law requires.

Respondent contends (Opp. 13) that the court of appeals' decision does not conflict with *Grocery Manufacturers of America, Inc.* v. *Gerace*, 755 F.2d 993 (2d Cir. 1985), because the federal requirement there arose from a regulation rather than "an informal letter." As explained above, the federal prohibition of warnings about methylmercury on tuna-product labels arises not merely from the Commissioner's letter, which reflects a culmination of FDA's preexisting policy. In any event, respondent's assertion that FDA's policy is insufficiently authoritative implicates the conflict

between the court of appeals' decision and *Dowhal*, which merits this Court's review.

Finally, respondent contends (Opp. 14) that, even if the FDA Letter carries the force of law, a warning other than the Proposition 65 warning that FDA rejected "could be crafted" that would not render tuna products misbranded under federal law. Respondent's position ignores the rationale for FDA's policy. As the Commissioner explained, FDA has chosen consumer advisories rather than product-label warnings to inform the public about the risks of methylmercury, because, among other reasons, a general warning could have "adverse public health consequences," including deterring non-vulnerable individuals from eating fish and obtaining the attendant health benefits. FDA Letter at 2-3. Moreover, a warning purporting to convey specific factual information about the harm caused by methylmercury (*e.g.*, that it "is known to cause cancer and reproductive harm," *id.* at 6) would lack "any scientific basis as to the possible harm caused by [tuna products], or as to the amounts of such foods that would be required to cause this harm." *Id.* at 6. Respondent's speculation that some type of warning could circumvent these concerns is unpersuasive.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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